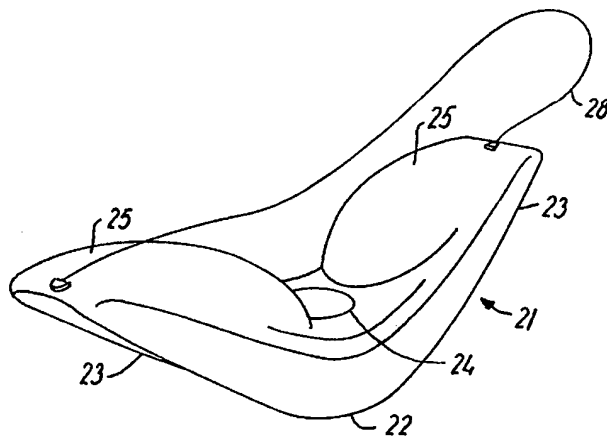




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/DK94/00311 <b>(22) International Filing Date:</b> 19 August 1994 (19.08.94) <b>(30) Priority Data:</b> 0951/93      20 August 1993 (20.08.93)      DK <b>(71) Applicant (for all designated States except US):</b> COLOPLAST A/S [DK/DK]; Bronzevej 2-8, DK-3060 Espergårde (DK). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> REIMER, Lotte [DK/DK]; Slotsbakken 100, DK-2980 Kokkedal (DK). <b>(74) Agents:</b> RAFFNSØE, Knud, Rosenstand et al.; Internationalt Patent-Bureau, Høje Taastrup Boulevard 23, DK-2630 Taas- trup (DK).		<b>(81) Designated States:</b> AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> <i>In English translation (filed in Danish).</i>

**(54) Title:** A DEVICE FOR ARRANGEMENT IN VAGINA FOR PREVENTION OF INVOLUNTARY URINATION WITH FEMALES AND AN APPLICATOR FOR USE IN INSERTION OF THE DEVICE

**(57) Abstract**

A device for prevention of involuntary urination in a female comprises an elastic body (21) designed for arrangement in the vagina for compressive action on and support of the neck of the bladder. The body (21) is made of a compressible material and comprises at least two projecting legs (23) joined in a flexible base (22) and is dimensioned in such a way that in the non-deformed state of the body the longest distance between the free ends of at least two legs exceeds the distance between the anterior wall and the posterior wall of the vagina. After the insertion of the body into the vagina in an elastically deformed state with the legs bent in a direction towards each other, an active pressure is thus exerted on the bladder neck. On their mutually facing sides, the legs are designed in such a way that in said elastically deformed insertion state they come into mutual contact for the provision of an increased elastic force of restitution. An applicator for insertion of the device comprises an elongated member having a proximal end and a substantially rod-shaped distal end portion for abutment with a bevel or a recess (24) formed in the angle between the legs of the device.

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A device for arrangement in vagina for prevention of involuntary urination with females and an applicator for use in insertion of the device

The present invention relates to a device for prevention of involuntary urination in a female, comprising a body designed for arrangement in the vagina and made of an elastic material for compressive action on and support of the neck of the bladder.

Stress incontinence is a nuisance experienced by up to one third of all women at some time or other during their lives.

Stress incontinence is often caused by a weakening or lack of control of the musculature of the pelvic floor, which results in the lack of support of the bladder neck and closure of the urethra.

Severe cases of stress incontinence are normally relieved by surgical intervention, while minor cases of stress incontinence can often be fully or partially relieved by training or retraining of the pelvic musculature.

Training or retraining of a pelvic muscle may, however, extend over many months and, as mentioned, may not in all cases relieve the problem completely.

It is therefore of great importance to find a product which can relieve stress incontinence.

The use of sanitary towels and napkins for relieving the inconveniences connected with involuntary urination is generally known. This, however, is a method associated with great disadvantages for the woman, as the sanitary towels are unhandy and voluminous, among other things.

Besides, it is known that stress incontinence may be relieved by the use of a tampon-like device which is

arranged in the vagina for compressive action and support of the neck of the bladder.

Such a device for relief of stress incontinence is known from, for example, US patent No. 4 019 498. This device consists of a body of compressible elastic material which is compressed and then placed in a bag. The bag with the body is inserted in the vagina, whereupon the bag is punctured. The body will then press against the neck of the bladder and in reality block the urethra. This method partly involves a cost-increasing component - the bag - and partly there is a risk of damaging the vagina and adjacent tissue when puncturing the bag.

Furthermore, it is impossible or difficult to adjust the position of the body after mounting in the vagina. Additionally, the body acts purely by the compressibility of the material, for which reason it is necessary to manufacture it in several different sizes.

EP-A-363421 also describes a device for arrangement in a woman's vagina with the object of relieving incontinence. This device also has the disadvantage that it acts as a support to the bladder neck merely in consequence of the compression taking place depending on the size of the vagina and the size of the body.

It is therefore also in this case necessary to manufacture different sizes to compensate for the different vaginal diameters.

Finally, EP-A-264258 describes an incontinence device - specifically for use in vaginal and rectal prolapse - designed as a U-shaped elastic body, which acts by lifting the neck of the bladder, wherein, after being arranged relatively far into the vagina close to the cervix, the body returns to its original position, and one leg of the U which is designed with a forked

structure, bears against the bladder/neck of the bladder which is lifted, whereby continence is obtained.

This is thus a relatively rigid structure, which is also designed in rather large dimensions.

5        This device, as well, is required to be manufactured in different sizes to compensate for the different vaginal diameters, as its lift is exclusively due to its shape, just as it is uncomfortable to wear owing to its rigid and fairly large structure.

10       A common feature of the above incontinence products is thus that it is necessary to manufacture the product in many different sizes to compensate for the various vaginal diameters.

15       This is partly economically inappropriate, and partly the body will not have an optimum function even after careful selection of size according to a woman's vaginal diameter, as the support by the bodies of the bladder neck will vary according to the physical posture of the woman and the state of tension of her pelvic  
20 muscle. There is thus a great risk that by use of the above-mentioned devices, the woman will still suffer from involuntary urination, and/or that the device will inconvenience, cause pain or even damage the vaginal mucous membrane, when the woman is in physical movement  
25 or tightens her pelvic musculature.

Thus, the known devices are economically unsuitable, just as they do not have an optimum function throughout their service life.

It is the object of the present invention to  
30 provide a device which comfortably relieves the nuisances indicated and thus secures the woman an optimum support regardless of her physical condition and which is at the same time easy to handle.

The device according to the present invention is  
35 characterized in that the body is compressible and

comprises at least two projecting legs joined in a flexible base and is dimensioned in such a way that in the non-deformed state of the body, the longest distance between the free ends of at least two legs exceeds the  
5 distance between the anterior wall and the posterior wall of the vagina, so that after the insertion of the body into the vagina in an elastically deformed state with the legs bent in a direction towards each other, an active pressure is exerted on the neck of the  
10 bladder, whereby the legs on the mutually facing sides are designed to come into contact with each other in said elastically deformed insertion state for the provision of an increased elastic force of restitution.

When using the device according to the invention,  
15 the compressive and elastic properties of the body are thus utilized together with its properties of restitution, the latter property arising when the legs of the body are pressed towards each other and will attempt to straighten out after insertion into the vagina.

20 Thus the neck of the bladder is partly supported by the action of the expansion force caused by compression of the body's material in the vagina between the anterior and posterior walls of the vagina and partly by the action of the force of restitution because the  
25 folded/bent-in body will attempt to straighten out between said walls.

The combination of the force of restitution and the force of expansion ensures that the product adapts to the varying spatial conditions in the vagina and always  
30 provides support for the bladder neck without blocking the urethra. The combination of the two forces also ensures that the product does not become unnecessarily large.

It will thus be possible to keep the resulting  
35 support of the bladder neck more stable in case of

variations of the vaginal diameter than with the known products.

This means that by use of the device according to the invention, it is possible to obtain a substantially optimum support of the bladder neck without risking exposure of the user to substantial inconveniences or pain or risks of damage to the vaginal mucous membrane.

Additionally, as a consequence of the above, it is possible to manage with a smaller number of sizes for the same user group, just as the product will be easier to insert and remove, as the device has smaller dimensions than the known ones to obtain a more optimum support.

As the body according to the present invention will spontaneously bend in the flexible base in case of folding, the body is easy to handle and to use correctly by the user herself.

Preferably, the device comprises two or three, particularly two, projecting legs which project at a mutual angle of more than about  $30^\circ$ , especially between  $90^\circ$  and  $150^\circ$ .

The device according to the invention may be provided with projecting legs which have a circular cross-section or are wedge-shaped in their outer shape.

In another preferred embodiment, the legs may be provided with a recess on the side facing the urethra and the neck of the bladder and have cushions formed on the opposite side. This makes it possible for the body to cradle the urethra/bladder neck, and it achieves greater compressive strength.

Additionally, on the side intended to face away from the urethra, the body may be provided with ribs in the flexible base periphery. This achieves a greater spring effect.

As a further possibility, the body may be hollow.

This has the result that the body cradles the urethra, as it is compressed most easily at the middle, and as the cross-section of the vagina is substantially shaped like a figure of eight, for which reason the body bears against the walls of the vagina to a higher degree. Additionally, the body need not be oriented at insertion.

The body may additionally be coated fully or partially with an elastic polymer film, such as polyethylene, polypropylene or polyvinyl chloride.

By coating with an elastic film, for example in the flexible base area, it is thus possible to increase the force of restitution of the body without changing the compressive properties of the legs.

The device according to the invention may be made of one or more materials, preferably comprising porous materials selected among polyvinyl alcohol or polyurethane, and wherein the compressive strength of the body is in the interval of 5-40 N - preferably 10-20 N - at a compression of the body to 50% of its thickness measured before compression.

The force of restitution of the body is in the interval of 1-10 N - preferably 1-5 N. The density is in the interval of 0.15-0.30 g/cm<sup>3</sup> - preferably about 0.20 g/cm<sup>3</sup>.

The body may be provided with a bevel or recess in the angle between the projecting legs to optimize the abutment of an applicator in connection with arrangement of the body in the vagina.

The invention also relates to an applicator for use at insertion of a device according to the invention provided with such recess, which applicator is characterized in that it comprises an elongated member having a proximal end and a substantially rod-shaped distal end portion for abutment with said bevel or recess.



The invention will now be described in further detail below with reference to the drawing, in which

Figs. 1-3 show a front and a side elevation and a perspective view of a first embodiment of the device,

5 Figs. 4-6 show an embodiment having three legs,

Figs. 7-12 show a third embodiment of the device,

Fig. 13 shows the arrangement of the device in the vagina for control of incontinence, shown in a sagittal cross-section,

10 Figs. 14-17 show an embodiment of an applicator for use in the arrangement of the device in the vagina, and

Fig. 18 another applicator embodiment.

Figs. 1-3 show a body 1 having a flexible base 2 and two projecting legs 3 positioned in the same plane.

15 The legs 3 have a circular cross-section, but may also have other cross-sectional shapes, such as oval, rectangular, etc.

The angle A between the two legs 3, measured between their axes of symmetry a and b is in the interval of 30°-180°, preferably 90°-150°, and depends on the length of the legs 3. Thus, a large angle renders possible a shortening of the length of the legs - all other things being equal - to obtain the same supporting effect.

25 The surface of the body 1 is smooth, and the angle between the two legs 3 may accommodate a plateau, a bevel or a recess 4, which an applicator (Fig. 14) may abut to facilitate arrangement of the body in the vagina. One leg or both legs 3 may be provided with a string 5 to facilitate removal of the body from the vagina and insertion of the body into the vagina in connection with the use of an applicator.

The diameter of the legs 3 of the body and the flexible base 2 is in the interval of 20-50 mm, preferably 25-35 mm, while the length of the legs 3, where

they are measured as the distance between the end point (a) of a leg and the point (b) determined as the point in which the axes of symmetry of the legs intersect each other, is in the interval of 30-70 mm, preferably 40-50 mm, these dimensions measured with the device 1 in a humidified state.

Before arrangement of the body 1 in the vagina, it is humidified, and the two legs are bent towards each other and pressed into the vagina with the arcuate portion first, where the legs will attempt to unfold and the compressed material will seek back to its state of rest. One leg 3 will press against the anterior wall of the vagina and against the bladder neck and support it, while the other leg 3 bears against the posterior vaginal wall.

The body 1 will follow the movements and dimensional changes occurring in the vagina, partly as a consequence of compression/decompression and partly owing to the force of restitution deriving from the two legs 3 of the body.

Figs. 4-6 show another embodiment, wherein the body 11 is provided with three legs 13, but otherwise has the same characteristic features as the one shown in Figs. 1-3.

The angle B between two legs measured from above (Fig. 5) is 120°.

When arranging this embodiment in the vagina, there is less tendency for the body 11 to "overturn", just as it is easier to position the body, as it need not be oriented.

The device 11 may also be manufactured with more than three legs 13 so that it almost assumes the characteristic of an "octopus".

When using an applicator as shown in Figs. 14-18, it is made to abut the recess 14 of the body 11, and the

string 15 from the latter is pulled up over the other end of the applicator.

Figs. 7-12 show a third embodiment of the body 21. Here shown with two legs 23, but could well have three or more legs.

Each leg 23 flattens out towards its end pole 23a to end in a wedge-like shape. This shape results in a smaller tendency for the body 21 to "overturn". Each leg 23 is provided with a cushion 25 constituting an integral part of the body 21. The cushion 25 is rounded in its shape and is arranged on the surface of the body 21 facing away from urethra. Providing the body 21 with such a bulge 25 results in higher compressive strength. Opposite to this bulge - on the outer side of the body 21 - there is possibly and primarily towards the front a recess 26 in each leg 3. The recess 26 causes the body 21 to cradle the urethra and imparts greater stability.

Additionally, on the side intended to face away from the urethra, the body 21 may be provided with ribs 27 at the periphery of the flexible base 22 and possibly extending fully or partially along the legs 23. This achieves a greater effect of restitution.

At the inner side of the flexible base 22, i.e., at the surface facing the opening of the vagina, a bevel, recess or shelf 24 serving as an abutment surface for an applicator 33 as shown in Figs. 14-18 may possibly be provided. The distal insertion end of the applicator is then positioned on the abutment surface 24. A string 28 fastened to each leg 3 is pulled back, whereby the body 21 folds about the applicator.

The body 21 is then inserted into the vagina by means of the applicator simultaneously with maintaining the pull in the string 28, and after positioning, the applicator is removed simultaneously with a cessation in the pull of the string 28. Then the body 21 will

attempt to unfold in the same manner as described above. All other things being equal, the cushions 25 will impart greater compressive strength to the body 21.

The thickness of the legs 23 of the body and the flexible base 22 is in the interval of 20-50 mm, preferably 25-35 mm, while the length of the legs 23 these being measured as the distance between the end point (a) of a leg and the point (b) determined as the point at which the axes of symmetry of the legs intersect each other, is in the interval of 30-70 mm, preferably 40-50 mm, and where these dimensions are measured with the device 21 in a humidified state.

The width of the device is in the interval of 10-40 mm, preferably 15-25 mm (also measured in a humidified state).

Fig. 13 shows the device of Figs. 7-12 in its position of use.

When the body 21 is positioned in the vagina 29, one leg with its full surface bears against the vaginal anterior wall 30 and supports the neck 31 of the bladder, whereby continence is achieved. The other leg bears against the posterior wall 32 of the vagina. Thus, the device does not completely fill the vagina.

The compressive strength of the body is in the interval of 5-40 N - preferably 10-20 N - at a compression of the body to 50 per cent of its thickness measured before compression. The force of restitution of the body is in the interval of 1-10 N - preferably 1-5 N (said values for the device in a humidified state).

The density of the material is in the interval of 0.15-0.30 g/cm<sup>3</sup>, preferably about 0.2 g/cm<sup>3</sup>.

Suitable materials for forming the above embodiments of the device are preferably formalized polyvinyl

alcohol and polyurethane, but other materials may also be applied.

A suitable polyurethane material is prepared by mixing a prepolymerized polyurethane with water. 0.5-3  
5 per cent, preferably 1-2 per cent, of a surface active additive has been added to the aqueous phase. A suitable surface-active additive is, for example, Emulgade 1000 Ni from Henkel. The polyurethane may be Hypol 2002 from Hampshire Chemical Corporation. The mixing ratio between  
10 the polyurethane component and the aqueous phase is selected so that there is an excess of polyurethane of 0-20 per cent - preferably 8-12 per cent. The material has the property that it expands by about 30 per cent when it is humidified, and it is a compressible, elastic  
15 material.

By manufacturing the body from this material, it is possible to obtain a saving on packaging, as the body takes up less space in a dry state than in the humidified state of use, and the body possesses good material  
20 properties rendering it pleasant for the user to utilize the body.

Figs. 14-18 show two embodiments of an applicator for use in the insertion of the above-described embodiments of the incontinence device into the vagina. In  
25 Figs. 14-17, the applicator comprises an elongated member 33 having a proximal end forming a finger grip 34 and a substantially distal end portion 35 being formed for abutment with the recess 24 at the rearwards facing side of the base 22 between the legs 23.

30 In the embodiment of Figs. 14-17, the member 33 has a substantially double concave, relatively flat cross-sectional profile along substantially most of its length. At the proximal end, the finger grip 34 is formed by means of a rib shape. To reduce friction and  
35 facilitate removal of the applicator after arrangement

of the device in the vagina, the distal end portion 35 is formed with smooth, plane or possibly slightly convex sides of the cross-sectional profile, as shown in Fig. 17.

5 In the embodiment of Fig. 18, the applicator comprises a cylindrical body 36 which is open at both ends and formed for receiving an incontinence device as shown in Figs. 7-12 in its elastically compressed  
10 insertion state with the flexible base 22 facing towards one open end of the member 36, which end is positioned in the opening of the vagina when the applicator is used. An elongated member 37 comprises at its proximal end a piston-like element 38, which fits the internal diameter of the cylindrical body 36 and is intended for  
15 insertion at the opposite end of the body 36, and a substantially rod-shaped distal end portion 39 which may be formed in the same manner as in the embodiment of Figs. 14-17. The piston-like element comprises a handle part projecting outside the applicator. In both embodi-  
20 ments, the distal insertion end 35, 39, respectively, may be designed for abutment also with the recesses 4 or 14 in the embodiments shown in Figs. 1-5. At a pull in the string 5, 15 or 28, the body will fold and be squeezed around the applicator, whereby the insertion  
25 is facilitated. In the embodiment of Fig. 18, the cylindrical body 36 may have an internal rib-shaped wall 40 to facilitate insertion, whereby the contact surface against the elastically deformed incontinence device is reduced and friction is lowered. The same effect may be  
30 obtained by means of a PTFE coating on the internal wall of the body.

## P A T E N T   C L A I M S

1. A device for prevention of involuntary urination in a female, comprising an elastic body (1, 11, 21) designed for arrangement in the vagina for compressive  
5 action on and support of the neck of the bladder, characterized in that the body (1, 11, 21) is made of a compressible material and comprises at least two projecting legs (3, 13, 23) joined in a flexible base (2, 12, 22) and is dimensioned in such a way that in the  
10 non-deformed state of the body, the longest distance between the free ends of at least two legs exceeds the distance between the anterior wall and the posterior wall of the vagina, so that after insertion of the body into the vagina in an elastically deformed state with  
15 the legs bent in a direction towards each other, an active pressure is exerted on the neck of the bladder, whereby the legs on the mutually facing sides are designed to come into contact with each other in said elastically deformed insertion state for the provision  
20 of an increased elastic force of restitution.

2. A device according to claim 1, characterized in that the legs (3, 13, 23) diverge at an angle between the axes of symmetry of the legs of more than about 30 degrees.

25 3. A device according to claim 1 or 2, characterized in that the angle (A) between the legs (3, 13, 23) is smaller than 180° and is preferably 90-150°.

4. A device according to claims 1, 2 or 3, characterized in that the body comprises three legs (13).

30 5. A device according to any one of the preceding claims, characterized in that the legs (3, 13) and the base (2, 12) have a substantially circular cross-section.

6. A device according to any one of claims 1-4,  
35 characterized in that the legs (23) are wedge-shaped.

7. A device according to any one of claims 1-4 or 6, characterized in that on the side which is intended to face the urethra when the body is inserted in the vagina, each leg (23) is provided with a recess (26) and on the opposite side with a cushion (25) constituting an integral part of the leg.

8. A device according to claim 7, characterized in that on the side intended to face away from the urethra, the body (21) is provided with ribs (27) in the periphery of the part comprising the flexible base (22) and fully or partially on the periphery of the legs (23), which ribs constitute an integral part of the device.

9. A device according to any one of the preceding claims, characterized in that the body is hollow.

10. A device according to any one of the preceding claims, characterized in that the body (1, 11, 21) is fully or partially coated with an elastic polymer film, such as polyethylene, polypropylene or polyvinyl chloride.

11. A device according to any one of the preceding claims, characterized in that the body (1, 11, 21) is formed in polyurethane or polyvinyl alcohol.

12. A device according to any one of the preceding claims, characterized in that the compressive strength of the body is in the interval of 5-40 N - preferably 10-20 N - at a compression of the legs folded together for mutual contact to 50 per cent of its total thickness measured before compression, and that the force of restitution of the body is in the interval of 1-10 N - preferably 1-5 N.

13. A device according to any one of the preceding claims, characterized in that the device is manufactured from a material the density of which is in the interval of 0.15-0.30 g/cm<sup>3</sup> - preferably about 0.20 g/cm<sup>3</sup>.



14. A device according to any one of the preceding claims, characterized in that it comprises a bevel or a recess (4, 14, 24) in the angle between the projecting legs (3, 13, 23), on which bevel or recess an applicator 5 (33) may abut for arrangement of the device in the vagina.

15. An applicator for use in the insertion into the vagina of a device according to claim 14, characterized in that it comprises an elongated member with a proximal 10 end and with a substantially rod-shaped distal end portion (35) for abutment with said bevel or recess (24).

16. An applicator according to claim 15, characterized in that the proximal end is provided with a finger 15 grip.

17. An applicator according to claim 15, characterized in that the proximal end forms a piston-like element, which fits into one end of a substantially cylindrical body (36) which is open at both ends and is 20 formed for receiving said device in its elastically deformed insertion state with the flexible base (22) facing towards the other open end of the body, whereby the piston-like element comprises a handle part (38) projecting outside the cylindrical body (36).

25 18. An applicator according to claim 17, characterized in that the internal wall (40) of the cylindrical body (36) is designed for reducing friction against the device.

19. An applicator according to any one of claims 30 15-18, characterized in that the distal end portion (35) of the body is designed for reducing friction against the mutually facing sides of the legs (3, 13, 23) of the device.

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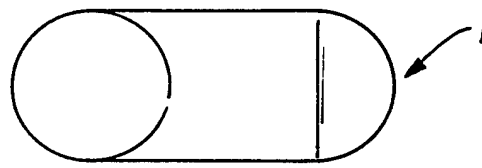


FIG. 1

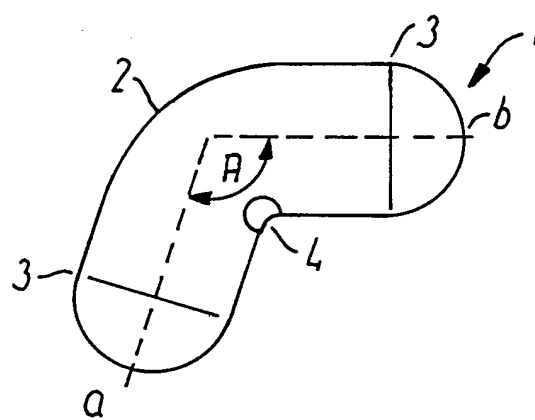


FIG. 2

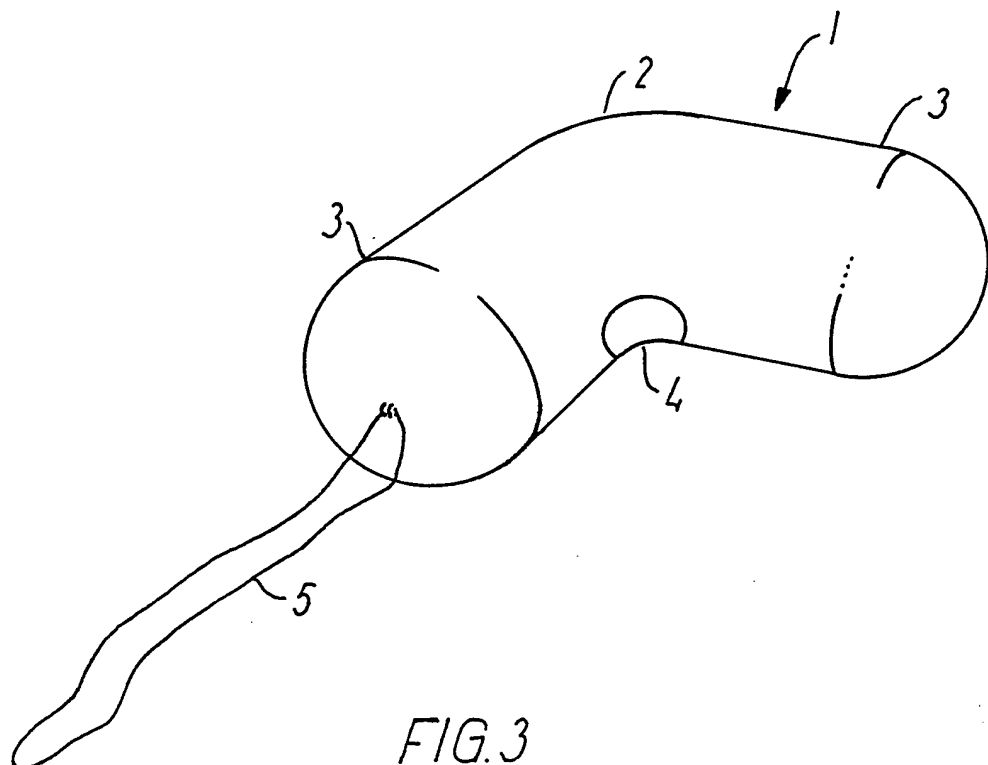


FIG. 3

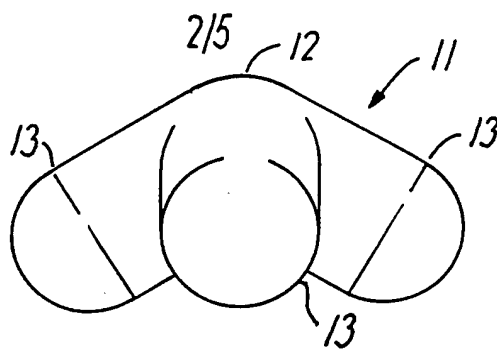


FIG. 4

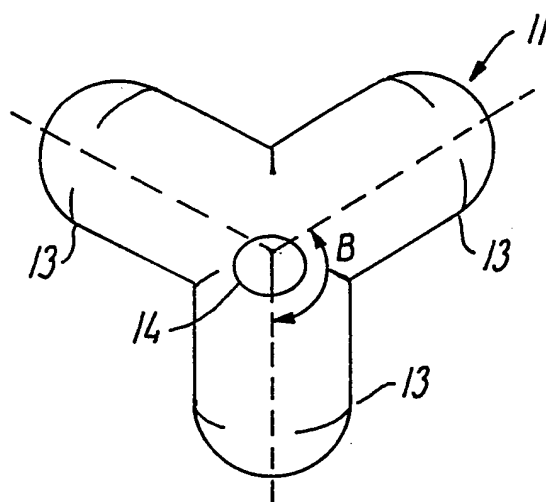


FIG. 5

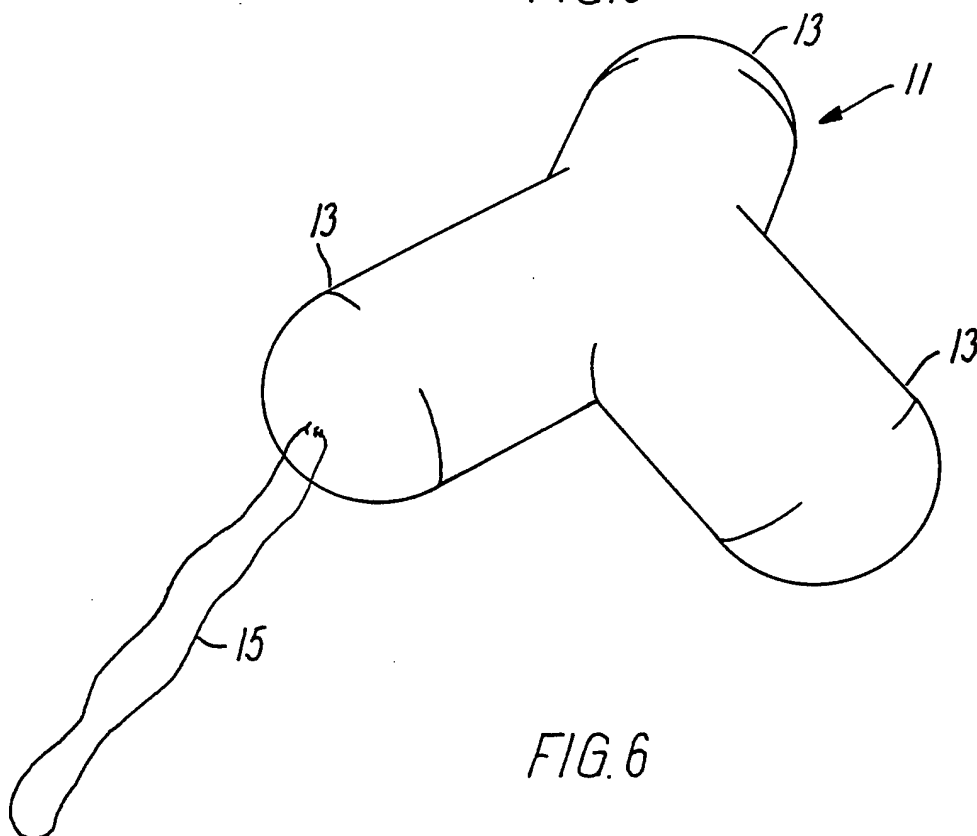


FIG. 6

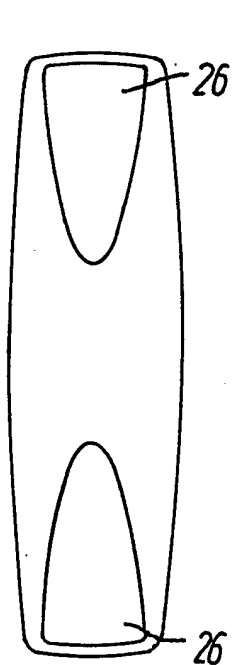


FIG. 7

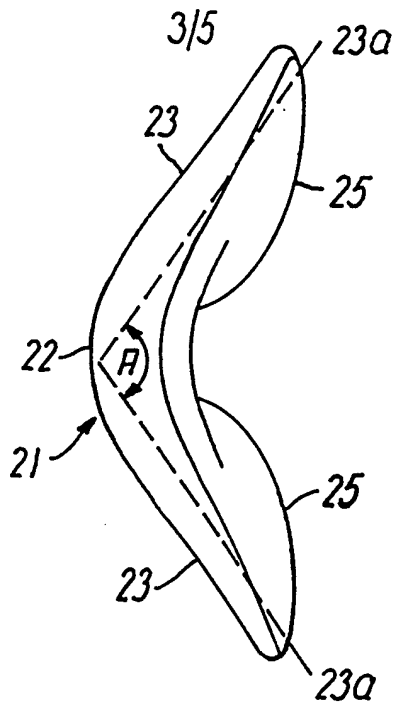


FIG. 8

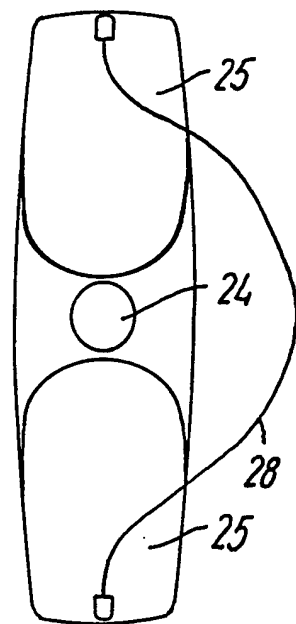


FIG. 9

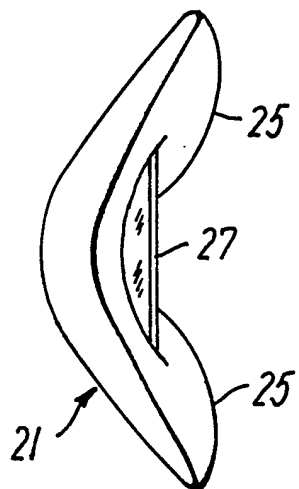


FIG. 10

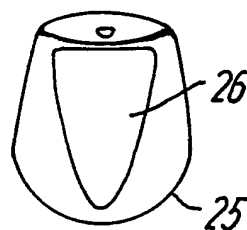


FIG. 11

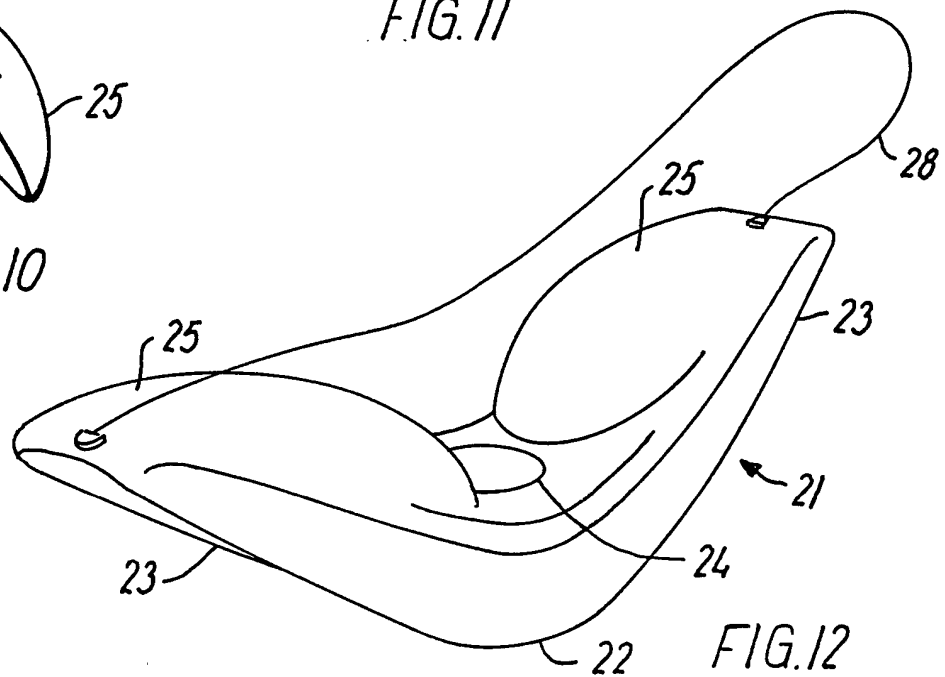


FIG. 12

4/5

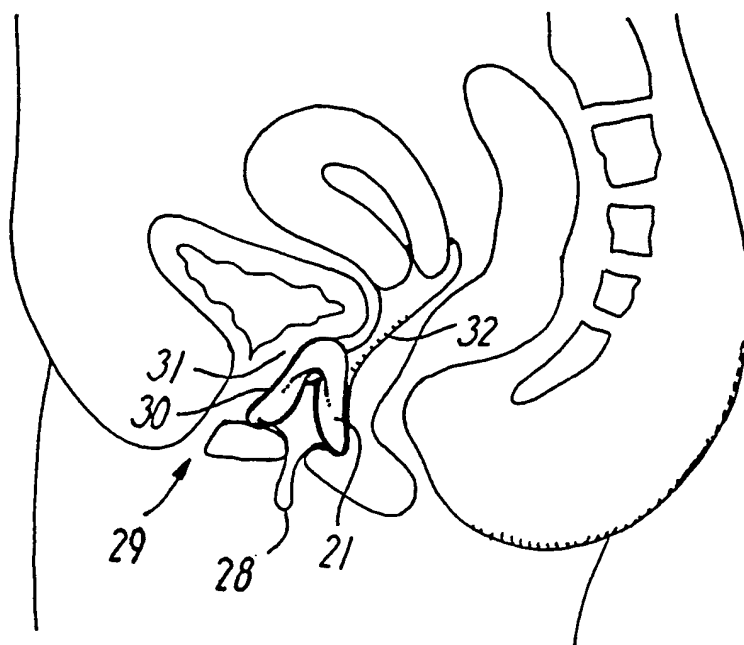


FIG. 13

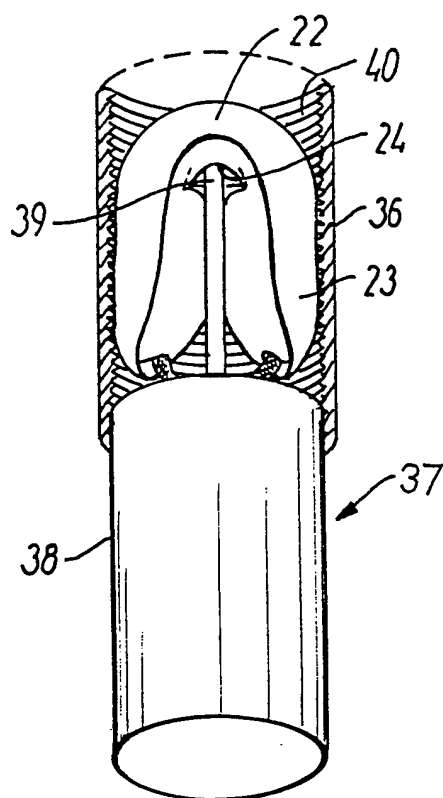


FIG. 18

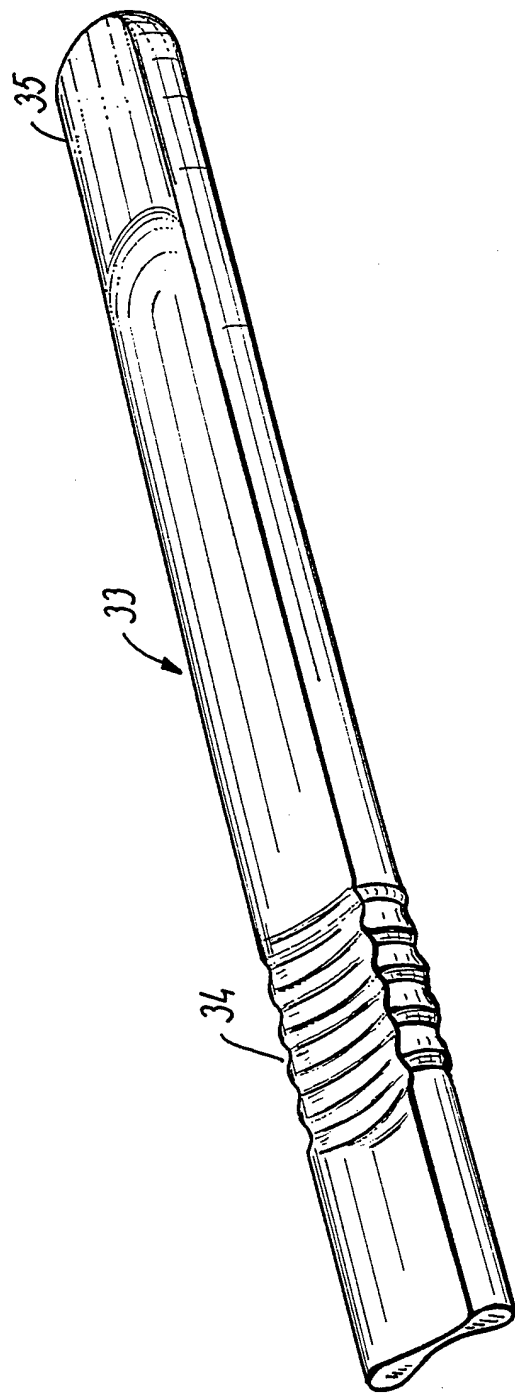


FIG. 14

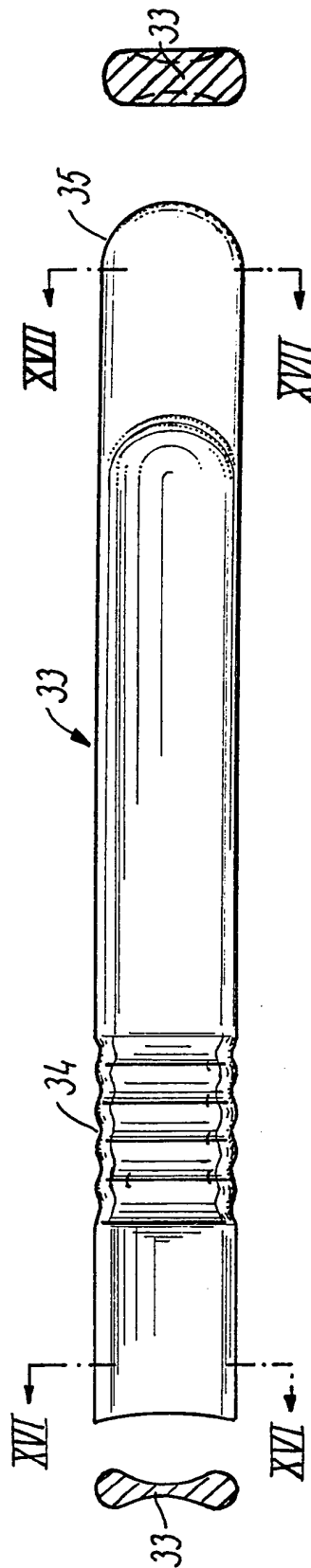


FIG. 16

FIG. 15

FIG. 17

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 94/00311

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/48, A61F 5/48

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## WPI, CLAIMS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5036867 (N. BISWAS), 6 August 1991 (06.08.91), column 3, line 14 - line 46, figures 1, 4 --	1-3,6-7,11
A	GB, A, 2147809 (THOMAS GEORGE EAKIN), 22 May 1985 (22.05.85), figures 1-2 --	1-3,11
A	US, A, 3554184 (H.N. HABIB), 12 January 1971 (12.01.71), figure 2 --	1-3,5-6
A	US, A, 4019498 (C.E. HAWTREY ET AL), 26 April 1977 (26.04.77), figures 1-5 --	1,5,11,15-16

☒ Further documents are listed in the continuation of Box C.
 ☒ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  16 December 1994	Date of mailing of the international search report  20 -12- 1994
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer  Leif Brander Telephone No. +46 8 782 25 00

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 94/00311

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4139006 (A.E. COREY), 13 February 1979 (13.02.79)  -- -----	1-3,5-7,9



**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

26/11/94

International application No.  
PCT/DK 94/00311

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5036867	06/08/91	EP-A,B- 0264258 SE-T3- 0264258 EP-A,B- 0362212 SE-T3- 0362212 JP-A- 63177852 US-A- 4920986 WO-A- 8909582	20/04/88  11/04/90  22/07/88 01/05/90 19/10/89
GB-A- 2147809	22/05/85	AU-A- 3438384 CA-A- 1242124 DE-A- 3473562 EP-A,B- 0157844 SE-T3- 0157844 GB-A,B- 2146901 US-A- 4875898 WO-A- 8501438	23/04/85 20/09/88 29/09/88 16/10/85  01/05/85 24/10/89 11/04/85
US-A- 3554184	12/01/71	NONE	
US-A- 4019498	26/04/77	NONE	
US-A- 4139006	13/02/79	NONE	